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| EXAMINER | |
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| AEDER, SEAN E | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/526,029 | YOUSEF ET AL. | |
| | Examiner | Art Unit | |
| | Sean E. Aeder, Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3,5,6,9-15,26 and 28-33* is/are pending in the application.

4a) Of the above claim(s) *13-15 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5,6,9-15,26 and 28-33* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/18/06*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## *Detailed Action*

The response filed on 10/13/06 to the restriction requirement of 9/15/06 has been received. Applicant has elected Group I for examination. Because Applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 3, 5, 6, 9-15, 26, 28-33 are pending.

Claims 13-15 and 33 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 3, 5, 6, 9-12, 26, 28-32 are currently under consideration.

## *Claim Objections*

Claim 3 is objected to for reciting: "...antibodies specifically reactive with kallikrein 5...". One of skill in the art would recognize that antibodies "specifically bind" and are not "specifically reactive with". It is suspected Applicant may intend claim 3 to recite: "...antibodies **that** specifically **bind** ~~**reactive with**~~ kallikrein 5...". Proper correction is required.

## *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 5, 6, 9-12, and 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is rejected for reciting: "A method as claimed in claim 5 wherein the kallikrein 5 is detected using antibodies....". It is unclear what is meant by a method "as claimed in claim 5". It is unclear whether claim 3 is drawn to a method further limiting the method of claim 5 or whether claim 3 is drawn to some method similar in some other way to one recited in claim 5. It is suspected Applicant *may* intend claim 3 to recite: "~~A method as claimed in~~ **The method of** claim 5, wherein the kallikrein 5 is detected using antibodies...".

Claims 5, 10, and dependent claims 3, 6, 11, 12, 29, 30-32 are rejected because claims 5 and 10 are indefinite for reciting: "a predetermined standard" or "levels for a predetermined standard". The specification and the claims do not distinctly claim what is meant by a predetermined standard. It is unclear exactly to what the "predetermined standard" refers. It is unclear how the exact numeric value of the "predetermined standard" or ""levels for a predetermined standard"" will be determined. It is further noted that claim 29 recites: "A method of claim 5 wherein the standard comprises normal levels of kallikrein 5 in samples of the same type obtained from control subjects not afflicted with breast or ovarian cancer". Claim 29 does not clarify what is meant by a "predetermined standard", as it is unclear precisely what is meant by "A method of claim

5" and "of the same type". Further, in regards to claim 29, it is unclear how a single standard can comprise multiple levels.

Claim 5 and dependent claims 6, 10-12, 29, 30, and 32 are rejected because claim 5 recites: "...where detection of a level of kallikrein 5 greater than that of a standard is indicative of breast or ovarian cancer". It is unclear how a level of kallikrein 5 greater than that of a standard is indicative of breast or ovarian cancer. For instance, it is unclear whether detection of a level of kallikrein 5 in a patient sample greater than that of some standard indicates that said patient has breast or ovarian cancer because kallikrein 5 levels are higher in patient samples that have breast or ovarian cancer, as compared to said standard. Alternatively, it is unclear whether detection of a level of kallikrein 5 in a patient sample greater than that of some standard indicates that said patient does not have breast or ovarian cancer because kallikrein 5 levels are lower in patient samples that have breast or ovarian cancer, as compared to said standard.

Claim 6 recites: "wherein the level of kallikrein 5 is ...the levels of the standard". There is insufficient antecedent basis for the term "the levels of the standard". Further, it is unclear how a single standard would have multiple levels.

Claim 9 and dependent claim 31 are rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claim 9 recites a method for monitoring the progression of breast or ovarian cancer comprising detecting

kallikrein 5 at two points in time and comparing levels of detected kallikrein 5; however, it is unclear what type of result is indicative of what type of progression. Thus, there is a missing step involving correlating a specific comparison to a type of progression of breast or ovarian cancer. See MPEP § 2172.01.

Claim 10 is rejected for reciting: "A method of claim 5 for screening a subject....". It is unclear what is meant by a method "of claim 5". It is unclear whether claim 10 is drawn to a method further limiting *the* method of claim 5 or whether claim 10 is drawn to some method similar in some other way to one recited in claim 5.

Claim 10 is rejected for reciting: "...(b) detecting the detectable substance thereby quantitating kallikrein 5 in the biological sample; and (c) comparing the quantitated kallikrein 5 with levels for a predetermined standard". It is unclear precisely *what* is being quantitated. Further, it is unclear how a predetermined standard has multiple levels. It is suspected Applicant may intend claim 10 to recite: "...(b) detecting the detectable substance thereby quantitating **the level of** kallikrein 5 in the biological sample; and (c) comparing the quantitated **the level of** kallikrein 5 **in the biological sample** with ~~**levels for**~~ a predetermined standard".

Claim 10 is rejected for being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Claim 10 recites a method for screening a subject for breast or ovarian cancer comprising detecting kallikrein 5 in a

sample and comparing the amount of kallikrein 5 in said sample to a predetermined standard; however, it is unclear what type of result is indicative of breast or ovarian cancer. See MPEP § 2172.01.

Claim 11 is rejected for reciting: "A method of claim 5 wherein the biological sample is serum....". It is unclear what is meant by a method "A method of claim 5". It is unclear whether claim 11 is drawn to a method further limiting *the* method of claim 5 or whether claim 11 is drawn to some method similar in some other way to one recited in claim 5. It is suspected Applicant *may* intend claim 11 to recite: "~~A~~ **The** method of claim 5, wherein the biological sample is serum....".

Claim 12 is rejected for reciting: "A method of claim 5 which further comprises....". It is unclear what is meant by "A method of claim 5". It is unclear whether claim 12 is drawn to a method further limiting *the* method of claim 5 or whether claim 12 is drawn to some part of the method recited in claim 5. It is suspected Applicant *may* intend claim 12 to recite: "~~A~~ **The** method of claim 5, ~~**which further comprises**~~ **further comprising**....".

Claim 28 is rejected for reciting: "A kit as claimed in claim 26 wherein....". It is unclear what is meant by a method "as claimed in claim 26". It is unclear whether claim 28 is drawn to a product further limiting the product of claim 26 or whether claim 28 is drawn to some product similar in some other way to one recited in claim 26. It is

suspected Applicant *may* intend claim 28 to recite: "~~**A kit as claimed in**~~ **The kit of**-claim 26 wherein....".

Claim 28 is rejected for reciting: "...protein fragments corresponding to kallikrein 5". It is unclear *how* protein fragments are to correspond to kallikrein 5. It is suspected Applicant may intend claim 28 to recite: "...protein fragments ~~**corresponding to**~~ **of** kallikrein 5".

Claim 29 and dependent claim 30 are rejected because claim 29 recites: "A method of claim 5 wherein the standard comprises normal levels of kallikrein 5....". It is unclear what is meant by "A method of claim 5". It is unclear whether claim 29 is drawn to a method further limiting *the* method of claim 5 or whether claim 29 is drawn to a method comprising some part of the method recited in claim 5. Further, it is unclear how a standard would contain multiple normal levels. It is suspected Applicant *may* intend claim 29 to recite: "~~**A**~~ **The**-method of claim 5 wherein the standard comprises **a** normal level~~**s**~~ of kallikrein 5....".

Claim 30 is rejected for reciting: "A method of claim 29 wherein the level....". It is unclear what is meant by "A method of claim 29". It is unclear whether claim 30 is drawn to a method further limiting *the* method of claim 29 or whether claim 30 is drawn to some part of the method recited in claim 29. It is suspected Applicant *may* intend claim 30 to recite: "~~**A**~~ **The** method of claim 29 wherein the level....".

Claim 31 is rejected for reciting: "A method of claim 9 wherein the biological sample....". It is unclear what is meant by "A method of claim 9". It is unclear whether claim 31 is drawn to a method further limiting *the* method of claim 9 or whether claim 31 is drawn to some part of the method recited in claim 9. It is suspected Applicant *may* intend claim 31 to recite: "~~A~~ **The** method of claim 9 wherein the biological sample ....".

Claim 32 is rejected for reciting: "A method of claim 10 wherein the biological sample....". It is unclear what is meant by "A method of claim 10". It is unclear whether claim 32 is drawn to a method further limiting *the* method of claim 10 or whether claim 32 is drawn to some part of the method recited in claim 10. It is suspected Applicant *may* intend claim 32 to recite: "~~A~~ **The** method of claim 10 wherein the biological sample ....".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 6, 9-12, 26, 28-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are

inclusive of a genus of kallikrein 5. However, the written description in this case only sets forth polypeptides comprising the amino acid sequence of SEQ ID NO:1. The specification does not disclose any other kallikrein 5 as broadly encompassed in the claims.

The specification teaches "kallikrein 5" encompasses naturally-occurring and recombinant variants of the polypeptide set-forth as SEQ ID NO:1 (see page 8, in particular). However, the written description only reasonably conveys polypeptides comprising the amino acid sequence of SEQ ID NO:1. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

As disclosed in the specification (see page 8), specific kallikrein 5 sequences are taught in the art. However, a representative number of naturally-occurring and recombinant variants of kallikrein 5 are not taught in the art.

The inventions at issue in Lilly were DNA constructs per se, the holdings of that case is also applicable to method claims such as those at issue here. A disclosure that

does not adequately describe a product itself logically cannot adequately describe a method of detecting that product.

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of sequences that encompass the genus nor does it provide a description of structural features that are common to the genus. Further, in regards to a genus encompassing variants, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. Since the disclosure fails to describe common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of SEQ ID NO:1 is insufficient to describe the genus. Thus, one

of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claims 3, 5, 6, 9-12, and 29-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting breast or ovarian cancer in a patient comprising obtaining a serum sample from said patient and detecting the level of kallikrein 5 (SEQ ID NO:1) polypeptide in said sample, wherein a higher level of kallikrein 5 (SEQ ID NO:1) polypeptide in said sample as compared to the level of kallikrein 5 (SEQ ID NO:1) polypeptide in serum from a subject that does not have breast or ovarian cancer indicates that said patient has breast or ovarian cancer, the specification does not reasonably provide enablement for a method of detecting breast or ovarian cancer in a patient comprising obtaining just any type of sample from said patient and detecting the level of just any kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in said sample, wherein a higher level of just any kallikrein 5 polypeptide, polynucleotide, or variant thereof as compared to just any type of standard is indicative of, in every way, breast or ovarian cancer (see claim 5). Further, the specification does not reasonably provide enablement for a method of monitoring the progression of breast or ovarian cancer comprising detecting levels of any kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in any sample (see claim 9). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in *Ex parte* Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in

the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The instant claims are broadly drawn to a method of detecting breast or ovarian cancer in a patient comprising obtaining just any type of sample from said patient and detecting the level of just any kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in said sample, wherein a higher level of just any kallikrein 5 as compared to just any type of standard is indicative of, in every way, breast or ovarian cancer (see claim 5). Further, the claims are broadly drawn to a method of monitoring the progression of breast or ovarian cancer comprising detecting levels of any kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in any sample (see claim 9).

The specification teaches a method of detecting breast or ovarian cancer in a patient comprising obtaining a serum sample from said patient and detecting the level of kallikrein 5 (SEQ ID NO:1) polypeptide in said sample, wherein a higher level of kallikrein 5 (SEQ ID NO:1) polypeptide in said sample as compared to the level of kallikrein 5 (SEQ ID NO:1) polypeptide in serum from a subject that does not have breast or ovarian cancer indicates that said patient has breast or ovarian cancer (see Figures 3 and 4, in particular).

The state of the prior art dictates that if a molecule such as a polypeptide comprising the polypeptide sequence set-forth in SEQ ID NO:1 is to be used as a surrogate for a diseased state, some disease state must be identified in some way with

the molecule. There must be some expression pattern that would allow the claimed polypeptide to be used in a diagnostic manner. For example, Tockman et al (Cancer Res., 1992, 52:2711s-2718s) teach considerations necessary in bringing a cancer biomarker (intermediate end point marker) to successful application. Tockman et al teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials (see abstract). Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and if validated (emphasis added) can be used for population screening (p. 2713s, col 1). The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease. This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point marker (p. 2714, see Biomarker Validation against Acknowledged Disease End Points). Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials (p. 2716s, col 2). Therefore, absent evidence of the polypeptide's expression in a particular type of sample including the correlation to

a diseased state and/or correlation to the progression of any disease, one of skill in the art would not be able to predictably use the polypeptides in any diagnostic setting without undue experimentation.

The level of unpredictability for the detection of any diseased state is quite high. Since neither the specification nor the prior art provide evidence of a universal association between the claimed method and every type of sample (including ocular lens fluid and saliva disclosed on page 7 of the specification) and every type of "predetermined standard" or control, and every type of kallikrein 5 (polypeptide, polynucleotide, or variant thereof), a practitioner wishing to practice the claimed invention would be required to provide extensive experimentation to demonstrate such an association. Such experimentation would in itself be inventive.

One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a method of detecting breast or ovarian cancer in a patient comprising obtaining just any type of sample from said patient and detecting the level of just any kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in said sample, wherein a higher level of just any kallikrein 5 as compared to just any type of standard is indicative of, in every way, breast or ovarian cancer and Applicant has not enabled said method because it has not been shown that levels of every kallikrein 5 (polypeptide, polynucleotide, or variant thereof) in every type of sample compared to just any standard would be indicative in every way breast or ovarian cancer. Further, one cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to a method of monitoring the

progression of breast or ovarian cancer comprising detecting levels of any kallikrein 5 in any sample and Applicant has not enabled said method because it has not been shown that changes in kallikrein 5 expression over time are indicative of progression of breast or ovarian cancer.

In view of the teachings above and the lack of guidance, workable examples and or exemplification in the specification, it would require undue experimentation by one of skill in the art to determine with any predictability, that the method would function as claimed.

***35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed (WO 99/18219; 4/15/99).

Reed et al teaches a polypeptide, KDP, 100% identical to instant SEQ ID NO:1 (kallikrein 5) (see attached sequence comparison). Reed et al further teaches a kit comprising antibodies that specifically bind KDP and fragments thereof (pages 12-13, in particular). Further, it is noted that claims 26 and 28 appear to contain statements reciting purpose or intended use. It is noted that statements of intended purposes or uses are not considered limitations because they merely state an intended use of the

invention rather than any distinct definition of any of the claimed invention's limitations (see Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999)). Thus, recitation of statements describing the claimed product as a product which is intended to be used to asses whether a subject is afflicted with breast or ovarian cancer are not given patentable weight and are not limitations to the claims.

***35 USC § 102(b)***

Claims 5, 6, 9, 29, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (British Journal of Cancer, 3/2/01, 84(5):643-50).

Kim et al teaches a method for detecting or screening a subject for ovarian cancer comprising obtaining a biological sample from a subject, detecting the amount of kallikrein 5 polynucleotide in said sample, and comparing said amount of kallikrein 5 polynucleotide detected to a predetermined standard comprising normal levels of kallikrein 5 polynucleotide a corresponding sample of the same type form control subjects not afflicted with ovarian cancer, where detection of the level of kallikrein 5 polynucleotide greater than that of a standard is indicative of ovarian cancer (Figure 1, in particular). Kim et al teaches a method wherein the level of kallikrein 5 polynucleotide is at least 5-20X the level of the standard/normal levels, as the standard/normal levels is undetectable (see Figure 1, in particular). Kim et al further teaches a method for monitoring the progression of ovarian cancer in a subject comprising detecting in a sample from the subject at a first time point kallikrein 5

polynucleotide, detecting kallikrein 5 polynucleotide at a subsequent time point, and comparing the levels of kallikrein 5 polynucleotide detected at each time point, and thereby monitoring the progression of ovarian cancer.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5, 6, 9, 12, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (British Journal of Cancer, 3/2/01, 84(5):643-50) as applied to claims 5, 6, 9, 29, and 30 above, and further in view of Magklara et al (Clinical Cancer Research, 4/2/01, 7:806-811).

The teaching of claims 5, 6, 9, 29, and 30 by Kim et al is described above; however, Kim et al does not specifically teach a method further comprising detecting kallikrein 8. However, this deficiency is made up in the teachings of Magklara et al.

Magklara et al teaches a method of detecting kallikrein 8 polynucleotide (page 807, in particular). Magklara et al further teaches kallikrein 8 polynucleotide is a diagnostic and prognostic marker for ovarian cancer (pages 808-809, in particular).

One of ordinary skill in the art at the time the invention was made would have been motivated to perform a method of detecting or screening a subject for ovarian cancer comprising obtaining a biological sample from a subject, detecting the amount of kallikrein 5 polynucleotide in said sample, and comparing said amount of kallikrein 5 polynucleotide detected to a predetermined standard, where detection of the level of kallikrein 5 polynucleotide greater than that of a standard is indicative of ovarian cancer, as taught by Kim et al, and detect kallikrein 8 polynucleotide alongside kallikrein 5 polynucleotide because Magklara et al teaches kallikrein 8 polynucleotide is a diagnostic and prognostic marker for ovarian cancer (pages 808-809, in particular) and one of skill in the art would recognize that methods of detection are more sensitive when using multiple markers for a particular condition. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining detecting kallikrein 8 polynucleotide when performing the method of Kim et al because Magklara et al teaches a method of detecting kallikrein 8 polynucleotide (page 807, in particular). Therefore, the invention as a whole would have been prima

facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

***Summary***

No claim is allowed.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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